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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PARENT APPLICATION OF: Allen *et al.*

APPLICATION No.: 10/821,021

FILED: April 7, 2004

FOR: THERAPEUTIC LIPOSOME COMPOSITION AND
METHOD OF PREPARATION

EXAMINER: Kishore, Gollamudi S.

ART UNIT: 1615

CONF. No: 9232

Supplemental Information Disclosure Statement After
First Office Action but Before Final Action or Notice of Allowance –
37 C.F.R. § 1.97(c)

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

1. Timing of Submission

The information transmitted herewith is being filed *after* three months of the filing date of this application or after the mailing date of the first Office action on the merits, whichever occurred last, but *before* the mailing date of either a final action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. §1.311, whichever occurs first. The references listed on the enclosed Form PTO-1449 (modified) may be material to the examination of this application; the Examiner is requested to make them of record in the application.

2. Cited Information

☐ All cited references are U.S. patents and publications, therefore no references are enclosed.

☒ Copies of the following references are enclosed:

- ☐ All cited references
- ☒ All cited references except U.S. patents and publications
- ☐ References marked by asterisks
- ☐ The following:

☐ Copies of the following references can be found in parent U.S. Application No. _____ :

☐ All cited references

01/17/2007 SSITHIB1 00000113 502207 10821021
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- ☐ References marked by asterisks
- ☐ The following:

- ☐ The following references are not in English. For each such reference, the undersigned has enclosed: (i) a translation of the reference; (ii) a copy of a communication from a foreign patent office or International Searching Authority citing the reference; (iii) a copy of a reference which appears to be an English-language counterpart; or (iv) an English-language abstract for the reference prepared by a third party. Applicant has not verified that the translation, English-language counterpart or third-party abstract is an accurate representation of the teachings of the non-English reference, though, and reserves the right to demonstrate otherwise.

- ☐ All cited references
- ☐ References marked by ampersands
- ☐ The following:

3. Effect of Information Disclosure Statement (37 C.F.R. § 1.97(h))

This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

4. Fee Payment (37 C.F.R. § 1.97(c)) or Certification (37 C.F.R. § 1.97(e))

- ☒ Applicant elects to pay the fee under 37 C.F.R. § 1.17(p) \$180.00.
 - ☒ Please charge the Deposit Account No. 50-2207 in the amount of \$180.00 (covering the fee under 37 C.F.R. § 1.17(p)).
- ☐ Applicant submits that no fee is due in light of the following certification under 37 C.F.R. § 1.97(e) (check only one):
 - ☐ In accordance with 37 C.F.R. § 1.97(e)(1), the undersigned hereby states that each item of information submitted herewith was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to this filing of this statement; or
 - ☐ In accordance with 37 C.F.R. § 1.97(e)(2), the undersigned hereby states that no item of information submitted herewith was cited in a communication from a foreign patent office in a counterpart foreign application, or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any

individual designated in 37 C.F.R. § 1.56(c), more than three months prior to the filing of this statement.

- ☒ Please charge any underpayment for timely filing of this paper to Deposit Account No. 50-2207.

5. Patent Term Adjustment (37 C.F.R. § 1.704(d))

- ☐ The undersigned states that each item of information submitted herewith was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this statement. 37 C.F.R. § 1.704(d).

Respectfully submitted,
Perkins Coie LLP

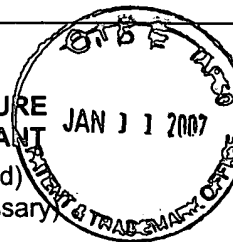
Date: 1.10.07

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
Form PTO-1449 (Modified)
(Use several sheets if necessary)



COMPLETE IF KNOWN

Application Number	10/821,021
Confirmation Number	9232
Filing Date	April 7, 2004
First Named Inventor	Allen, <i>et al.</i>
Group Art Unit	1615
Examiner Name	Kishore, Gollamudi
Attorney Docket No.	55325-8148.US07

Sheet 1 of 2

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	U.S. Patent or Application		Name of Patentee or Inventor of Cited Document	Date of Publication or Filing Date of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		NUMBER	Kind Code (if known)			
	1.	5,426,112		Zagon <i>et al.</i>	06/20/05	
	2.	5,719,032		Vielkind, Juergen R.	2/17/98	
	3.	5,840,687		Harkins <i>et al.</i>	11/24/98	
	4.	6,056,973		Allen <i>et al.</i>	5/2/00	
	5.	6,129,916		Chang, Tse Wen	10/10/00	
	6.	6,224,903		Martin <i>et al.</i>	5/1/01	
	7.	6,936,272		Martin <i>et al.</i>	8/30/05	
	8.	7,122,202		Allen <i>et al.</i>	10/17/06	
	9.	2003/0215490	A1	Allen <i>et al.</i>	11/20/03	
	10.	2004/0191307	A1	Allen <i>et al.</i>	9/30/04	
	11.	2004/0191250	A1	Allen <i>et al.</i>	9/30/04	
	12.	2005/0136064	A1	Allen <i>et al.</i>	6/23/05	
	13.	2005/0169880	A1	Glick <i>et al.</i>	8/4/05	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent or Application			Name of Patentee or Applicant of Cited Document	Date of Publication or Filing Date of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Office	NUMBER	Kind Code (if known)				
	14.	EPO	0 932 391	B1	Sequus Pharm., Inc.	5/2/03		
	15.	PCT	WO 94/22429	A3	Liposome Technology, Inc.	09/29/94		
	16.	PCT	WO 98/16202	A3	Sequus Pharm., Inc.	4/23/98		

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application(s).

INFORMATION DISCLOSURE STATEMENT BY APPLICANT Form PTO-1449 (Modified) (Use several sheets if necessary)				COMPLETE IF KNOWN	
				Application Number	10/821,021
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Sheet	2	of	2	Attorney Docket No.	55325-8148.US07

OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published.	T	
	17.	Ahmad <i>et al.</i> , "Antibody-mediated Specific Binding and Cytotoxicity of Liposome-entrapped Doxorubicin to Lung Cancer Cells <i>in Vitro</i> ", <i>Cancer Research</i> , <u>52</u> :4817-4820 (1992).		
	18.	Allen <i>et al.</i> , "Liposomes containing synthetic lipid derivatives of poly(ethylene glycol) show prolonged circulation half-lives <i>in vivo</i> ", <i>Biochimica et Biophysica Acta</i> , <u>1066</u> :29-36 (1991).		
	19.	Behr, Jean-Paul, "Gene Transfer with Synthetic Cationic Amphiphiles: Prospects for Gene Therapy", <i>Bioconjugate Chem.</i> , <u>5</u> :382-389, (1994).		
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	21.	Carter <i>et al.</i> , "High Level <i>Escherichia coli</i> Expression and Production of a Bivalent Humanized Antibody Fragment", <i>BioTechnology</i> , <u>10</u> :163-167, (1992).		
	22.	Felgner <i>et al.</i> , "Enhanced Gene Delivery and Mechanism Studies with a Novel Series of Cationic Lipid Formulations", <i>The Journal of Biological Chemistry</i> , <u>269</u> (4):2550-2561, (1994).		
	23.	Gao <i>et al.</i> , "Cationic liposome-mediated gene transfer", <i>Gene Therapy</i> , <u>2</u> :710-722, (1995).		
	24.	Heath, T., <i>et al.</i> , <i>Experimental Cell Research</i> , <u>149</u> :163-175 (1983).		
	25.	Klibanov, A.L., <i>et al.</i> , <i>FEBS Letters</i> , <u>268</u> (1):235-237 (1990).		
	26.	Lear and Rafalski, Viral Fusion Mechanisms, J.Bentz (ed), CRC Press, Boca Raton, pgs. 56-66 (1993).		
	27.	Lee and Low, <i>Biochimica et Biophysica ACTA</i> , <u>1233</u> :134-144 (1995).		
	28.	Maruyama, K., <i>et al.</i> , <i>Proc Natl Acad Sci USA</i> , <u>87</u> :5744, (1990).		
	29.	Mayhew <i>et al.</i> , "Role of Cholesterol in Enhancing the Antitumor Activity of Cytosine Arabinoside Entrapped in Liposomes", <i>Cancer Treatment Reports</i> , <u>63</u> (11-12):1923-1928, (1979).		
	30.	Plum <i>et al.</i> , "Condensation of DNA by Trivalent Cations. 2. Effects of Cation Structure", <i>Biopolymers</i> , <u>30</u> :631-643, (1990).		
	31.	Remy <i>et al.</i> , "Gene Transfer with a Series of Lipophilic DNA-Binding Molecules", <i>Bioconjugate Chem.</i> , <u>5</u> :647-654, (1994).		
	32.	Sinha, D., <i>et al.</i> , <i>Biochem. Biophys. Res. Comm.</i> , <u>90</u> (2):554 (1979).		

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